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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/017,223	12/14/2001	R. Martin Emanuele	19720-0229 (42896/263913)	9686

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EXAMINER	
SCHNIZER, RICHARD A	

ART UNIT	PAPER NUMBER
1635	9

DATE MAILED: 07/21/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/017,223	EMANUELE ET AL.	
	Examiner	Art Unit	
	Richard Schnizer, Ph. D	1635	

-- The MAILING DATE of this communication appears on the cover she t with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on *09 May 2003* .

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☐ Claim(s) *36-41* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) *36-41* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *04 June 2002* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

An amendment was received and entered as Paper No. 8 on 5/9/03.

Claims 36-41 remain pending and are under consideration in this Office Action.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970);and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 36-41 stand rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over the following U.S. Patents.

Instant claims rejected	Patent No.	Patented claims	Supporting specification passage
36-41	6,359,014	1, 2, 5, 6, 11, 16	Col. 14, lines 9-31.
36-41	RE37,285	1, 7	Col. 15, lines 20-45
36, 38, and 40	5,674,911	1	Col. 7, lines 9-13; col. 15, lines 11-17

Although the conflicting claims are not identical, they are not patentably distinct from each other because the issued claims are drawn to copolymer compositions for treating patients, and to methods for treating patients by administering the copolymers, wherein the copolymers have physical characteristics falling within the ranges recited in the instant claims. The instant claims are broadly drawn to methods of preventing cell damage wherein the only active method step is the administration to a patient of a copolymer of the same physical characteristics as those in the issued patents. Because the issued and pending claims each teach methods in which identical compositions are delivered by identical method steps, and the pending claims include no method steps that are not recited in the issued claims, the results of the issued and pending methods must be the same. For this reason, the issued claims render the pending claims obvious.

Response to Arguments

Applicant's arguments filed 5/9/03 have been fully considered but they are not persuasive.

Applicants arguments from page 5 through page 7 line 2 of the response are based on the position that a rejection founded on a conclusion that claims in an application differ from claims of a base "parent" patent only in an obvious manner must be supported by a citation of an additional reference that represents prior art relative to

the application claims. Applicant cites *In re Brathwaite*, *In re Longi*, and *In re White and Langer* in support, but fails to indicate any passage from any of these decisions which supports the argument. Applicant's attention is directed to MPEP 804 (II)(B)(1) which discusses obviousness-type double patenting. While the factual inquiries to be applied when considering obviousness type double patenting involve consideration of both the prior art and the claims of the potentially conflicting patent, there is no stated requirement that any rejection must rely on any secondary reference in the prior art. In fact, the MPEP provides Form Paragraph 8.34 entitled "Rejection, Obviousness Type Double Patenting – No Secondary Reference(s)", which was used to set forth the instant rejection. A second form paragraph is provided for situations in which the issued patent itself is not sufficient to support an obviousness rejection, and a secondary reference must be relied upon as well (see Form Paragraph 8.36). Because Applicant failed to provide any evidence that one must rely on a secondary prior art reference in an obviousness type double patenting rejection, and because the MPEP provides a form paragraph for the purpose of making obviousness type double patenting rejections without secondary references, Applicant's argument is unpersuasive.

At pages 6 and 7 of the response, Applicant argues that the instant claims are not rendered obvious by the '285 and '014 claims because no genus species relationship was cited in the rejection, noting that a double patenting rejection can be maintained when the patent claims a species element and the application claims a broad genus. This argument does not overcome the rejection because all that is

required for obviousness-type double patenting is that a pending claim must be an obvious variant of an issued parent claim. Applicant has provided no evidence that the parent claim must be a species and the pending claim must be drawn to a genus. In this case, the methods are obvious variants because they recite performing the same method steps with the same materials, necessitating the same outcome. In any event, the patented claims are clearly species of the instant claims because the method steps of the instant claims require administering a copolymer to a patient "at risk for cell damage". Clearly, anyone who is alive is *at risk* for cell damage merely by virtue of living. Living organisms must take in a variety of compounds that place them at risk for cell damage including, for example, molecular oxygen. Thus patients with pathologic hydrophobic interactions ('014 patent), humans with sickle cell anemia ('285 patent), and humans or animals with infections ('911 patent) are all within the genus of "patients at risk for cell damage."

At page 7 of the response Applicant notes that the instant claims are drawn to methods of preventing cell damage, whereas the claims of '911 are directed to methods of treating an infection caused by a microorganism. Applicant asserts that the inventions are independent and distinct. However, this assertion lacks any support such as the need for a separate and non-coextensive search or different classification of the claimed methods. In fact, the claimed methods, while not coextensive in their intended effects, recite exactly the same method step, i.e. delivery to a patient of a composition comprising a block copolymer. As such the methods will have similar

effects. Because Applicant provided no evidentiary or reasoned support that the inventions are independent and distinct, the rejection is maintained.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 36-41 stand rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 36-41 are indefinite because it is unclear what is intended by "substantially pure" and "non-pure". Claims 36, 37, 40, and 41 require a substantially pure composition that is less toxic than a corresponding non-pure composition, whereas claims 38, 39, and 42 require tat the purer composition must have less unsaturation. One of skill in the art cannot know the metes and bounds of the invention because the specification fails to define "substantially pure" or "non-pure", and does not provide any standard of comparison that would allow one to make these determinations. Consider the following hypothetical example. One has three compositions which are 30%, 50% and 90% pure, respectively, and toxicity of the compositions decreases with increasing purity. None of these compositions is 100% pure, so it is not clear if any of them is substantially pure, on the other hand it cannot be known if any or all are considered to be non-pure. If one does not know whether or not 50% pure is "substantially pure", then one cannot know whether the 50% pure composition is within the metes and bounds of the claims. The 50% pure composition is purer and less toxic than the 30% pure

composition, but it is less pure and more toxic than the 90% pure composition. Do the claims embrace the 50% pure composition or not?

The claims are also indefinite because the method steps are not concordant with the purpose set forth in the preamble. The methods require prevention of cell damage, but recite no step at which damage is prevented.

Response to Arguments

Applicant's arguments filed 5/9/03 have been fully considered but they are not persuasive.

Applicant argues at pages 8 and 9 of the response that the claims provide a definition of the term "substantially pure". This is unpersuasive because this definition is non-limiting and requires only that a substantially pure block copolymer must contain copolymers of a certain chemical formula and polydispersity. This definition does not limit what other impurities might also be in the composition, and which could be considered in the definition of purity. For this reason the rejection is maintained. Applicant's arguments concerning issued language in the '014 and '241 patents are unpersuasive because they do not address the logical basis of the rejection.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the

applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

(f) he did not himself invent the subject matter sought to be patented.

Claims 36, 38 and 40 stand rejected under 35 U.S.C. 102(e) as being anticipated by Emanuele et al (US Patent 5,674,911).

Emanuele teaches methods of treating infections in a human or animal by administering a POE/POP block copolymer comprising a POE portion between 1,200 and 15,00 D and wherein the POE portion represents about 1-50% of the weight of the copolymer. See claim 1. The polydispersity of the copolymer may be 1.05. See column 15, lines 14-17. The copolymer is less toxic than corresponding prior art compositions, and is substantially free of unsaturated molecules. See column 6, lines 22-27. Because it is free of unsaturated molecules, the composition is considered to be substantially pure. The compound can be used to protect against damage to tissue cells by ameliorating infection.

Thus Emanuele anticipates the claims.

Claims 36, 38, and 40 stand rejected under 35 U.S.C. 102(f) because the applicant did not invent the claimed subject matter.

These claims were rejected under 35 USC 102(e) over US Patent 5,674,911 to Emanuele et al for the reasons set forth above. The '911 patent lists two inventors not listed on the instant Application (Balasubramanian and Allaudeen) ad the instant application lists two inventors not listed on the '911 patent (Hunter and Culbreth). For this reason, it is not clear who has invented the claimed methods.

The Assignee is required to either name the first inventor of the conflicting subject matter or show the inventions were commonly owned at the time of Applicant's invention.

Response to Arguments

Applicant's arguments filed 5/9/03 have been fully considered but they are not persuasive.

Applicant argues at pages 9 and 10 of the response that the cited patent fails to teach or suggest a method of preventing cell damage as claimed in the instant application. This argument is unpersuasive because the issued claims are a species of the instantly claimed genus. The issued claims require administration to a human or animal with an infection caused by a microorganism of a composition comprising block copolymers with the physical characteristic recited in the instant claims. The instant claims require administration to a patient at risk of cell damage of a composition comprising a block copolymer. Clearly the human or animal in the issued claims is at risk of cell damage as a result of infection. Applicant has presented no reason or evidence that the issued claims would not result in the effects set forth in the instant claims. For these reasons, the rejections are maintained.

Conclusion

No claim is allowed.

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner(s) should be directed to Richard Schnizer, whose telephone number is 703-306-5441. The examiner can normally be reached Monday through Friday between the hours of 6:20 AM and 3:50 PM. The examiner is off on alternate Fridays, but is sometimes in the office anyway.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, John Leguyader, can be reached at 703-308-0447. The FAX numbers for art unit 1632 are 703-308-4242, and 703-305-3014. Additionally correspondence can be transmitted to the following RIGHTFAX numbers: 703-872-9306 for correspondence before final rejection, and 703-872-9307 for correspondence after final rejection.

Inquiries of a general nature or relating to the status of the application should be directed to the Patent Analyst Trina Turner whose telephone number is 703-305-3413.

Scott D. Priebe

Richard Schnizer, Ph.D.

SCOTT D. PRIEBE, PH.D
PRIMARY EXAMINER